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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,012	01/31/2002	Velizar T. Tchernev	21402-258 (Cura 558)	8120

7590 06/29/2006
Ivor R. Elrifi, Ph.D.
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Glovsky and Popeo, P.C.
One Financial Center
Boston, MA 02111

EXAMINER

BAUSCH, SARA E L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/072,012

Applicant(s)

TCHERNEV ET AL.

Examiner

Sarae Bausch

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

DETAILED ACTION

Election/Restrictions

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-4, 38, 41 drawn to polypeptide, classified in class 530, subclass 350.
 - II. Claims 5-14, 39, 42 drawn to nucleic acid, classified in class 536, subclass 23.1.
 - III. Claim 15-17, 40, 43, drawn to antibody, classified in class 424, subclass 130.1.
 - IV. Claims 18, drawn to method for determining amount presence of polypeptide, classified in class 435, subclass 69.1.
 - V. Claim 19-21, 46-47, drawn to determining the presence of a nucleic acid, classified in class 435, subclass 6.
 - VI. Claim 22-25 drawn to identifying an agent that binds to a polypeptide, classified in class 435, subclass 69.3.
 - VII. Claims 26-29, 48, drawn to method of treating by administration of a polypeptide, classified in class 514, subclass 21.
 - VIII. Claims 30-33, 39, 42, drawn to method of treating by administration of a polynucleotide, classified in class 514, subclass 44.
 - IX. Claims 34-37, 49, drawn to method of treating by administration of an antibody, classified in class 424, subclass 178.1.
 - X. Claims 44-45, drawn to method of determining presence of disease by polypeptide, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I-III are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of group II is composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The polypeptide of group I is composed of amino acids linked by peptide bonds and can assume complex tertiary structures. While the antibody of group III is also composed of amino acids linked by peptide bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. The products of groups I-III can be used in materially different processes, for example the DNA of group II can be used in hybridization assays, the antibody of group III can be used in immunoassays, the polypeptide of group I can be used to make a fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups I-III are patentably distinct from each other.

Inventions of group IV-X are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of group IV comprise steps which are not required for or present in the method of : determining the presence of a nucleic acid (group V), contacting a polypeptide with an agent (group VI), administration of polypeptide (group VII), administration of a nucleic acid (group VIII), administration of antibody (group IX), detecting a polypeptide in a mammal (group X). The end result of the methods are different: determining the amount of a polypeptide (group IV), determining the

Art Unit: 1634

amount of a nucleic acid (group V), identifying an agent that binds a polypeptide (group VI), treating disease with polypeptide (group VII), treating a disease with a nucleic acid (group VIII), treating a disease with an antibody (group IX), determining presence of a disease with a polypeptide (group X). Thus, the operation, function, and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different groups are patentably distinct.

Inventions I and V, VIII, IX, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions the methods of group V, VIII, IX, identify and administer a nucleic acid or antibody which does not require the use of the polypeptide of group I.

Inventions II and IV, VI, VII, IX, X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions the methods of group IV, VI, VII, IX, X identify and administer a polypeptide or antibody which does not require the use of the nucleic acid of group II.

Inventions III and IV, V, VII, VIII, X, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions the methods of group IV, V, VII, VIII, X, identify and administer a polypeptide or nucleic acid which does not require the use of the antibody of group III.

Inventions I and IV, VI, VII, and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the polypeptide of group I can be used to purify proteins or make a fusion protein with a nucleic acid, which is not required for any of the method of group IV, VI, VII, and X.

Inventions II and V, VIII, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acid of group II can be used to for purification of nucleic acid, in situ hybridization, or encoding proteins, which is not required for the method of group V, VIII.

Inventions III and VI & IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibody of group III can be used in immunoassays or for purification of a protein which is not required for the method of group VI and IX.

2. Please note, if group II is elected claims 39 and 42 will be read to the extent that the claims are drawn to a product. The limitation of a pharmaceutical composition will not be given

Art Unit: 1634

patentably weight and will not be considered for this examination. If group VIII is elected, claims 39 and 42 will be examined to the extent that they are used in the method of group VIII.

3. Additionally, each group named above is subject to further restriction. Applicant is required to further elect a specific SEQ ID NO. This is NOT an election of species. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, “[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.” 35 U.S.C. 121. Pursuant to this statute, the rules provide that “[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted.” 37 CFR 1.142 (a). See also 37 CFR 1.141(a). Searching more than one of the claimed patentably distinct sequences represents a serious burden to the office.

4. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

5. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Art Unit: 1634

6. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1634

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

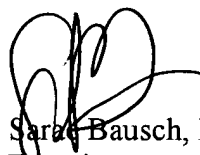
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



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Art Unit 1634